

K082937
P1/A

MAR 11 2009

SECTION E - 510(k) SUMMARY

(Optional Format 3-10-98)

510(k) Summary This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

Submitter Physio - Control, Inc.
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P.O. Box 97006
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Date Prepared March 2, 2009

Name LIFEPAK® 15 Monitor/ Defibrillator

Common Name Low Energy DC - Defibrillator: Class II

**Device
Classification**

Classification Name	Class
Low-Energy DC – Defibrillators	Class II
Cardiac Monitors (including Cardiometer and Rate Alarms)	Class II
External Transcutaneous Cardiac (non-invasive) Pacemaker	Class II
Oximeter	Class II
Automated External Defibrillator	Class III
Noninvasive Blood Pressure Measurement System	Class II
Blood Pressure Computer	Class II
Carbon Dioxide Gas Analyzer	Class II

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Predicate Device(s) The features and functions of the LIFEPAK 15 monitor/defibrillator are substantially equivalent to the previously cleared LIFEPAK 12 defibrillator/monitor. Listed in Table 1 are the respective 510(k) numbers and clearance dates.

Table 1

510(k) Number	Clearance Date
K063510	01/26/07
K041459	07/01/04
K040775	04/23/04
K033275	11/06/03
K010918	03/26/01
K002445	01/31/01
K990338	09/01/99
K991910	06/03/99
K973486	01/09/98

Performance Standards This 510(k) includes documentation related to the verification and validation of the LIFEPAK 15 monitor/defibrillator.

Device Description The LIFEPAK 15 monitor/defibrillator is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols.

Intended Use The LIFEPAK 15 monitor/defibrillator is intended for use by trained medical personnel in out-of doors and indoor emergency care settings within the environmental conditions specified. The LIFEPAK 15 monitor/defibrillator is designed to be used during ground transportation except when specified otherwise. Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients.
Automated external defibrillation mode is intended for use on patients eight years of age and older.

Indications for Use Manual Defibrillation
Indications
Manual defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic

SECTION E: 510(k) SUMMARY

ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Contraindications

Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

Automated External Defibrillation

Indications

AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 15 monitor/defibrillator is not intended for use on pediatric patients less than eight years old.

Noninvasive Pacing

Indications

Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications

Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

12-lead Electrocardiography

Indications

The 12-lead electrocardiogram is used to identify, diagnose and treat patients with cardiac disorders and is useful in the early detection and prompt treatment of patients with acute ST-elevation myocardial infarction (STEMI).

Pulse Oximetry

Indications

Pulse oximetry is indicated for use in any patient who is at risk of developing hypoxemia, carboxyhemoglobinemia, or methemoglobinemia. SpO₂ monitoring may be used during no motion and motion conditions, and in patients who are well or poorly perfused.

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SpCO and SpMet accuracies have not been validated under motion or low perfusion conditions.

Noninvasive Blood Pressure Monitoring

Indications

Noninvasive blood pressure monitoring is intended for detection of hypertension or hypotension and monitoring BP trends in patient conditions such as, but not limited to, shock, acute dysrhythmia, or major fluid imbalance.

End-Tidal CO₂ monitoring

Indications

EtCO₂ monitoring is used to detect trends in the level of expired CO₂. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully.

Invasive Pressure Monitoring

Indications

Invasive pressure monitoring is indicated for use in patients who require continuous monitoring of physiological pressures in order to rapidly assess changes in the patient's condition or response to therapy. It may also be used to aid in medical diagnosis.

Technological Characteristics

The LIFEPAK 15 monitor/defibrillator product is a next generation product to the currently legally marketed LIFEPAK 12 defibrillator/ monitor product. The LIFEPAK 15 monitor/defibrillator design is significantly based upon the existing LIFEPAK 12 architecture and when compared to the LIFEPAK 12 predicate it has similar performance characteristics, features, and accessories.

Conclusion

The information in this 510(k) demonstrates that the LIFEPAK® 15 Monitor/Defibrillator, is substantially equivalent to the identified predicate devices with respect to safety, effectiveness and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

Physio - Control, Inc
c/o Ms. Teresa Davidson
11811 Willow Road Northeast
P.O. Box 97006
Redmond, WA 98073-9706

Re: K082937
Lifepak 15
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (Three)
Product Code: MKJ, LDD, DRT, DRO, DQA, DXN, DSK, CCK
Dated: March 2, 2009
Received: March 4, 2009

Dear Ms. Davidson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

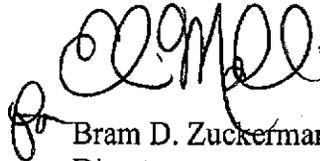
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D - STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K082937

Device Name: LIFEPAK® 15 Monitor/Defibrillator

Indications for Use:

Manual Defibrillation

Indications

Manual defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Contraindications

Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

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Indications

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Indications

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082937

SECTION D - STATEMENT OF INDICATIONS FOR USE

Pulse Oximetry

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Invasive Pressure Monitoring

Indications

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Prescription Use
 (Part 21 CFR 801 Subpart D)

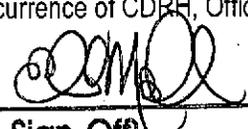
AND/OR

Over-The-Counter Use _____
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)



(Division Sign-Off)

Division of Cardiovascular Devices

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